Lessons Learned from TSCA Section 6 Draft Risk Evaluations: Some observations from industry

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Objective

In 2016 the Toxic Substances Control Act (TSCA) was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) and those changes were welcomed as a change in how we do business - both for EPA and for industry

EPA, industry, and other stakeholders must:

- work in partnership to make LCSA successful, achieve the stated goals, and increase public confidence in chemical technology

- share the responsibility for successful implementation of the TSCA amendments

Some overarching challenges

Use of tiered approaches

Occupational exposure assessment

- Coordination with OSHA
- Addressing uncertainty and variability

Uncertainty how Risk Evaluations (RE) will lead into Risk Management (RM)

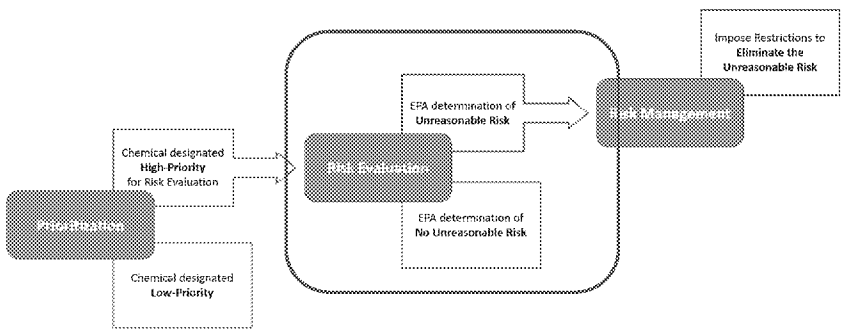
Overview of process

Formal opportunities to comment

- 45-day comment period for draft Scope document
- 60-day comment period on the draft Risk Evaluation (RE)

Informal opportunities to comment

- EPA open to discussions with stakeholders throughout the process



Dockets established for first 10 chemicals subject to RE

Chemical Name	CASRN	Chemical Group	Docket Number(s)
Asbestos	1332-21-4	N/A	EPA-HQ-OPPT-2016-0736
1-Bromopropane	106-94-5	Solvents	EPA-HQ-OPPT-2019-0235
Carbon Tetrachloride	56-23-5	Solvents	EPA-HQ-OPPT-2019-0499
1,4 Dioxane	123-91-1	Solvents	EPA-HQ-OPPT-2019-0238
Cyclic Aliphatic Bromide Cluster (HBCD)	25637-99-4; 3194-55-6; 3194-57-8	Flame retardants	EPA-HQ-OPPT-2019-0237
Methylene Chloride	75-09-2	Solvents	EPA-HQ-OPPT-2019-0437
N-Methylpyrrolidone (NMP)	872-50-4	Solvents	EPA-HQ-OPPT-2019-0236
Perchloroethylene	127-18-4	Solvents	EPA-HQ-OPPT-2016-0732
Pigment Violet 29	81-33-4	Solvents	EPA-HQ-OPPT-2018-0604
Trichlorethylene (TCE)	79-01-6	Solvents	EPA-HQ-OPPT-2016-0737 EPA-HQ-OPPT-2019-0500

Agenda

This presentation will focus more on technical aspects of the draft RE using examples primarily relating to human exposure assessment

- Some positives, more detail on the challenges
- Specific examples of ways to move forward
- Looking forward
- Take-home messages

Challenges

- Application of tiered approaches
- EPA assessment of occupational exposure
  - How are EPA and OSHA working together?
  - There is uncertainty and variability in describing conditions of use (COU)
  - Uncertainty often addressed by use of worst-case values that results in findings of unreasonable risk
  - Evaluation of occupational non-users
- How will the RE lead into Risk Management (RM)?
  - Will EPA set occupational exposure limits that differ from OSHA?

Positives

- EPA has done a lot of work under tight legislative deadlines
- Conceptual models provide good road-maps for each RE
- Use of higher tier tools
  - Monte Carlo probabilistic exposure modeling
  - PBPK models to derive chemical specific internal exposure
  - Models that account for the impact of evaporation on dermal exposure (IHSkinPerm, TCE/consumers p 137)
- Sensitivity analysis

Tiered approaches

EPA has incorporated higher tier modeling tools (Monte Carlo, PBPK)

Such approaches could be improved for example for the PBPK models

- Providing further detail in selection of the inputs
- Conducting sensitivity analysis

EPA applied IHSkinPerm to consumer exposures and should consider its utility in worker exposure assessment

Occupational exposure assessment

- There are many ways to ensure that occupational exposures are controlled appropriately
  - Different combinations of factors including weight fraction, mass of material handled, how the material is handled, ventilation, PPE etc… can lead to a "safe" exposure
  - This applies to hazardous chemicals, i.e. many sets of operating conditions can be defined that maintain exposure below a selected threshold
- Companies should consider submitting detailed descriptions of controls in the workplace along with Industrial Hygiene (IH) monitoring data
  - Need for contextual, i.e. narrative information ('meta data') to improve data analysis and make sure data is interpreted correctly

Occupational exposure assessment

Managing exposure to existing chemicals in the workplace historically falls under OSHA

Companies often establish administrative and engineering controls to manage worker exposure

- Requires expert judgment to assess the specific combination of factors in a particular workplace to assess exposure potential

Need transparency around coordination with OSHA

Occupational exposure assessment

- Unreasonable risks have been identified for some occupational non-users (ONU)
  - For Carbon tetrachloride, *"The determinations reflect the hazards associated with the occupational exposures to carbon tetrachloride and the expected absence of PPE for ONUs. The driver for EPA's determinations of unreasonable risk for ONUs is cancer from chronic inhalation exposure." (p. 21)*
  - *"There is uncertainty in the ONU inhalation risk estimate since the data did not distinguish between worker and ONU inhalation exposure estimates." (p. 167)*
  - Highlights the need for detail describing submitted data
  - Additionally, data submitters should provide information on how any relevant OSHA Substance Specific Standards are implemented, for example if those standards limit proximity for ONU to the chemical of interest (i.e., Regulated Areas)

Occupational exposure assessment

- Manufacturers and downstream users must engage with each other and with EPA to understand how products are used throughout the value chain
- Need for well-defined exposure scenarios
  - What are the activities in which workers are engaged?
  - What are the duration and frequency of tasks?
  - Narrative information and metadata are important!

Challenges in dermal risk assessment

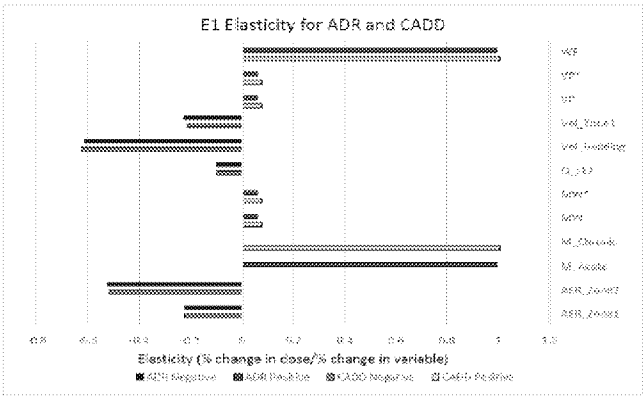
- Lack of monitoring data for dermal exposure leads to use of conservative assumptions – high end calculation for N-methylpyrrolidone (NMP) assumes full contact with both hands and no glove use *(NMP RE, p. 163, 272)*
  - There is uncertainty about the extent of glove use amongst workers - lack of gloves leads to unreasonable risk finding, but with certain gloves, risk is controlled for some conditions of use
  - Information on glove use practices may be obtainable data for some conditions of use (COU) to address this uncertainty
  - Semiconductor industry submitted data and information to address the initial unreasonable risk finding for use of NMP as a solvent Use in Electrical Equipment, Appliance and Component Manufacturing *(https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0031)*
    - Published data can inform and/or refine the risk assessment (see for example, "Using physiologically-based pharmacokinetic modeling to assess the efficacy of glove materials in reducing internal doses and potential hazards of N-methylpyrrolidone during paint stripping" C. R. Kirman in *Journal of Exposure Science & Environmental Epidemiology)*

Looking forward

Two examples of how information in the draft RE can be used to inform data and analysis in the future

Example 1 - Sensitivity analysis

- Use of sensitivity analysis identifies key data that will impact the output (example shown here is an exposure estimate)



Figure_Apx D-1. Elasticities (≥ 0.05) for Parameters Applied in E1

ADR = acute dose rate
CADD = chronic average daily dose

most sensitive parameters (+ve elasticity)
WF (weight fraction)
M_acute (mass of product used)

next most sensitive parameters (negative elasticity)
Vol_Building (building volume);
AER_Zone2 (air exchange rate in Zone 2);
AER_Zone1 (air exchange rate in Zone 1);
Vol_Zone1 (room of use, or Zone 1 volume).

Example from page 516/517
https://www.epa.gov/sites/production/files/2020-02/documents/1_draft_risk_evaluation_for_trichloroethylene_tce_public.pdf

Example 2 - Environmental releases

- The Toxic Release Inventory (TRI) is an important source of chemical release information for EPA
- Reported volumes are initially treated as actual volumes released and used in a site-specific risk assessment
  - Example TCE: "Releases modeled using E-FAST 2014 were predicted based on engineering site-specific estimates, as based on DMR, TRI, and/or CDR databases" -

DMR = discharge monitoring report
CDR = chemical data reporting

Example 2 - Environmental releases

- Companies can run their own TRI, DMR, and/or CDR reporting data through the E-FAST tool (publicly available) to understand potential conclusions that might be drawn from the data. *(TCE RE page 265)*

Name, Location, and ID of Active Releaser Facility [a]	Release Media [b]	Modeled Facility or Industry Sector in EFAST [c]	EFAST Waterbody Type [d]	Days of Release [e]	Release (kg/day) [f]	7Q10 SWC (ppb) [g]	COC Type	COC (ppb)	Days of Exceedance (days/year) [h]	Risk Quotient
							Algae (HC_{05})	52,000	0	0.00
	Surface Water	NPDES TX0072168	Still body	350	0.000095	9.50	Acute	3,200	NA	0.00
							Chronic	788	0	0.01
							Algae	3	350	3.17
							Algae (HC_{05})	52,000	0	0.00
				20	0.002	200.00	Acute	3,200	NA	0.06
							Chronic	788	0	0.25
							Algae	3	20	66.67
							Algae (HC_{05})	52,000	0	0.00

Download E-FAST (free) https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014 and other models https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate

Application of tiered approach

E-FAST is a conservative screening approach

EPA subsequently used VVWM-PSC model to refine exposure estimates for scenarios with initial risk quotient > 1

We generally encourage more use of tiered approaches

VVWM-PSC = Variable Volume Water Model – Point Source Calculator

Looking to the future

- Risk management (RM) - still uncertain on how this will work
  - Focus on conditions of use that lead to unreasonable risk findings, but what degree of risk will be basis for RM? Worst case?
  - How will EPAs approaches to RM fit in with existing OSHA requirements?
  - Even when RM does not include a ban, it can increase reporting burden such as triggering 12b notification, changing SDS language, tracking volumes, etc…
  - Impact anywhere along the value chain - so need for engagement throughout

Looking to the future

- Expect an increased emphasis on general population (GP) exposure in the next 20 RE
- For example, there are several phthalates in the 20 substances which will next undergo RE, which have conditions of use that may result in GP exposure
  - Pathways for general population exposure include (but not limited to) drinking water, groundwater, indoor air, ambient air, fish ingestion, human breast milk, dust and soil

Looking to the future

- Increased use of biomonitoring data
- How will the data be interpreted and incorporated into a risk assessment context?
  - For example, for CAS 84-61-7, (dicyclohexyl phthalate) "reasonably available literature and databases suggests that human biomonitoring data exist, including a CPSC (2010) study which showed that in the United States, the 2001–2002 National Health and Nutrition Examination Survey (NHANES) measured metabolites of dicyclohexyl phthalate in urine."

Looking to the future

- Data call-ins: EPA has several mechanisms (beyond CDR and TRI) by which to gather data on chemicals
  - TSCA § 8 Data call-ins
  - TSCA § 4 Test Orders for PV 29 require parties to conduct solubility testing and to conduct dust sampling *(docket: https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2020-0070-0002&contentType=pdf)*
  - It is in data-holders' interest to present the most accurate and complete information on conditions of use and potential exposures sooner rather than later
  - Conduct a sensitivity analysis to understand which data may have higher impact and where additional resource could have most impact in the RE

Take-home messages

- There are a myriad of manufacturing operations, so it is to the benefit of the impacted industries to provide information regarding their processes, particularly with respect to the activity pattern of workers leading to potential exposures
  - Include information about the engineering controls (e.g., ventilation), administrative controls, and PPE implemented by your company (see for example *https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0031)*)
- Share data and information on your chemistry and how it's used
  - In the instance of exposure data, yes, we need to work through CBI questions, but this should not prevent engagement

Take-home messages

- Don't just 'throw data over the wall' - assess and present it
  - Companies / consortia can run their own risk evaluations to identify where assumptions are used to fill data gaps, and where data or refinement is needed
  - Provide contextual information
  - Consider drafting a conceptual model of the chemical lifecycle for the conditions of use of interest
- Consider the hierarchy of data quality (i.e. data > modeling > occupational exposure limits or release limits) and apply systematic review criteria
- Need for engagement across the value chain

Take-home messages

- Interested parties should review scoping documents to understand the proposed boundaries of the new RE
  - This is an important opportunity to comment on conditions of use
  - Analysis Plan and conceptual model identify data and information gaps
- Get your data and models peer reviewed and published as much as possible - this will help EPA to rely on publicly available data and information;

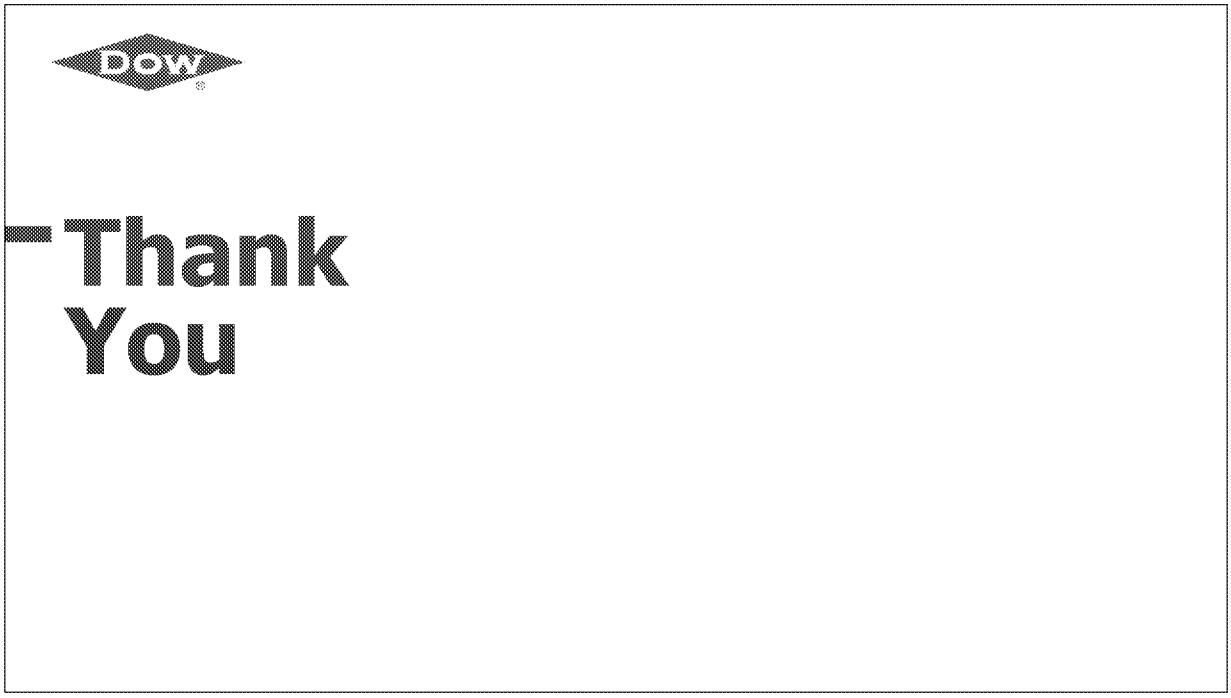
Conclusion

There are opportunities for both EPA and regulated industry to learn from the first 10 draft RE to increase and improve collaborative discussions, thereby improving the effectiveness of amended TSCA.

There are both formal and informal opportunities for interacting with EPA and sharing data, BUT,

Ongoing challenges remain, including (but not limited to)

- Application of tiered approaches
- Working through worker exposure assessment and collaboration with OSHA
- Transparency on Risk Management


Thank
You